Total Quality Management: An Epidemiologist's Frank Perspective

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The aim of science is not to open the doors to everlasting wisdom but to close the doors to everlasting ignorance."—Bertolt Brecht (Galileo)

If quality health care were the end point and if we could define it, the question would be, is total quality management (TQM) the "cause" of quality health care?

In epidemiology, the cause of an outcome is an area of great discussion. For example, if I ask you what causes a nosocomial urinary tract infection (UTI), some of you might respond *Escherichia coli*; others may cite the fact that a Foley catheter was in place for 6 days; others, the presence of diarrhea in an elderly, demented patient who is unable to sustain good hygiene; still others may incriminate the underlying diabetes mellitus or poor catheter management and contamination by health care workers as the cause.

Who is right? Possibly all or several. We have come to use the notion of "risk factor" today to define a set of variables more likely to occur in clinical cases than in appropriately-matched control cases. We use statistics to define "more likely." We use multivariate analysis to define independent predictors of the end point, the nosocomial UTI in this example.

Fortunately, we have a good definition of a nosocomial UTI. By good, I mean operationally useful, broadly accepted, and with important clinical meaning. The concept of a UTI is simple. The risk factors seem limited.

Quality health care, by contrast, is elusive. We say we know it when we see it; we can give excellent examples. But no definition is user-friendly, broadly accepted, simple; and risk factors for quality health care seem infinite.

Yet around the country we are asked to accept the statement that TQM causes quality health care. On the surface, this is a nice idea but totally without proof: There are (1) no clinical trials in which hospitals have been randomized to incorporate TQM or no TQM; (2) no observational cohort studies in which hospitals with TQM versus those without TQM have been shown to have different levels of quality; (3) no case-control studies in which hospitals with well-defined quality have been compared with those of poor quality and in which TQM was examined as a risk factor. We are asked to accept it, because it is reasonable and idealistic and because some excellent examples support the notion.

In response to this harsh conclusion, TQM experts may say, "Well, I agree it is not *the* cause, but it is, in your language, a risk factor."

To identify a risk factor, however, there must be a case-control study—cases with the outcome of interest matched to control cases without the outcome of interest—and then some acceptable analysis must be performed. To qualify we would need hospitals with high quality of care, if we agreed on the definition, matched with control hospitals with "low" quality of care, and we would have to examine for risk factors. Will the high quality institutions be over-represented by the variable, TQM? Can we measure TQM? How much TQM will meet the definition?

After analyzing the hypothetical study described above, imagine that the *P* value for TQM is ≤.05, ie, statistically significant. At that point, there are four possibilities:

1. It is true that TQM leads to quality health care.

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2. It is not true and only appears to be so because of chance or random error.

3. It is not true and only appears to be so because of confounding or linked variables, eg, case severity differences.

4. It is not true and only appears to be so because of some bias, some systematic error in design, perhaps a bias in selection of control subjects or actual cases, favoring the outcome.

Such a study, therefore, would have to account for chance, confounding, and bias. Perhaps, all of this is moot, because no such data exist. We have no data to support the idea that TQM leads to quality health care. Yet, you are asked to accept the statement because it is reasonable, sounds idealistic, and because some excellent examples support the notion.

To be fair, in epidemiology, we often have to assess probable cause and outcome relationships. The type of thinking is called causal inference, and many authors, including Henle, Koch, and more recently Evans,[1-3] have helped to define the elements of cause: temporality, consistency, high association, biologic plausibility, specificity, and biologic gradient.

Temporality means that the putative cause always precedes the effect: eating the contaminated food always precedes and does not follow typhoid fever. Consistency implies that repeated observation of the relationship is observed. High association means the cause is more likely if the odds ratio or relative ratio is high, eg, 4 or greater. Biologic plausibility means that known biologic mechanisms are reasonably supportive of the relationship. A high-fat diet may lead to elevated lipids, and lipid levels are a marker for risk of myocardial infarction. Specificity implies that the introduction of the risk factor leads to the outcome, and withdrawal of the risk factor leads to an absence of the effect. Biologic gradient implies a dose-response curve: the more of the risk factor, the greater the outcome.

Let us apply the principles of causal inference to TQM and quality health care, again assuming each could be defined. Does a hospital with excellent quality care exist without TQM? Do all hospitals with poor quality have no element or few elements of TQM? Is this a consistent observation in various situations? Do we know the odds ratio for TQM and the outcome of interest—quality health care? With all the complexities of human behavior, is TQM plausible as the cause of quality care? If a hospital has TQM and if the TQM is removed, will good quality be followed by poor quality care? Lastly, is it true that with more TQM activities we see progressively more quality of care in a dose-response fashion?

The answers are unknown, maybe, or not at all. Thus, epidemiologists are forced reluctantly to conclude that, using the elements of causal inference, there currently is no support for the statement that TQM leads to high quality health care.

To be fair to TQM proponents, I now entertain the response, "Well, maybe we do not yet have definitive proof, but it is a damn good idea. You have no proof for any other system favoring excellent health care delivery, and besides it doesn't hurt!" I think that TQM is a good idea, and I know of no proof for another system, but I would like to examine the notion that "it doesn't hurt." Proponents of TQM are dedicated, vigorous, and outspoken about their beliefs. Some of the most outspoken, however, see no room for alternatives, ie, see a single risk factor—TQM. Epidemiologists have to be concerned that an outcome as complex as quality health care would have a single risk factor—that it would not be multifactorial in fact. Those who leave no room for either alternatives or additions may, in fact, hurt by thwarting the discovery of other important risk factors.

Perhaps as objectionable is the small but vocal component of TQM—the "religious right wing component" of TQM—that know they are right, know that nonbelievers are wrong, and know that nonbelievers should and will suffer eternal fires or at least some administrative fires while laboring in the life of this career.

As an epidemiologist, I am concerned not about the effects of chance or confounding but instead what might be called the administrative effects of bias-systematic error. Thus, the idea that unbridled TQM cannot hurt can be challenged, in my opinion, because there may be adverse effects, in some instances, both to individuals and to populations who voice opposition or question the value of TQM.

From the perspective of epidemiology, I conclude that we have no proof from intervention studies, observational cohort studies, or case-control studies supporting TQM, that we cannot invoke the principles of causal inference to support TQM, and that there is some risk of harm.

My real concerns with the way TQM is practiced in some institutions are (1) the top-down, paternalistic approach; (2) the failure to focus sufficient attention on the cultural chain of events; and (3) the frequent failure to consider the value of the individual over the system.

Many health care workers are frustrated that the system pays only lip service to concerns of the staff and even sometimes the concerns of the patient. They have the impression that upper management knows what is needed, determines the agenda for TQM, and focuses so much on its bottom line that the value of care becomes less important than the bottom line. These are anecdotes to be sure, but they are large enough in size and replicated often enough to give me concern.

Communication is so critical in the complex care in a hospital or clinic, and often little attention is given to the specific language of

interacting disciplines. Recognizing this aspect of communication, several management groups have coined the term and supported the approach called "sociotechnical systems" to get at specific components.[4] These systems examine what I have called the "cultural chain of events" and must be examined more carefully in health care delivery. How clearly does a physician communicate with a nurse or clerk in a clinic? How well do any of these individuals communicate with the clinic scheduling person? These are important cultural events for a hospital system attempting to deliver high quality care.

Lastly, let me address what I think is most important—the quality of the individual. The unique qualities of the individual health care worker are more important than any environment, any structure, and any system of management.[5]

I have now led you from my thinking as an epidemiologist to my thinking as a single health care worker, and I would be remiss if I did not respond in my role as an investigator. What do I think of TQM? I think it is an exciting idea, a testable (but difficult) hypothesis, an important experiment to carry out. I applaud people like Don Berwick[6] for pushing us to think about this system, to use it, to measure its effects.

I have moved to the Medical College of Virginia/Virginia Commonwealth University to become the individual I often have teased—the administrator. As chairman of the department of internal medicine, what do I think of TQM? It is a vitally important concept and needs to pervade the institution. We need to try to improve continually; we need to measure the outcomes of our actions; we need to know and address the concerns of all stakeholders.

We must begin by admitting what we know in fact, acknowledging what we do not know, remaining open to alternatives and additional ideas, and promoting a great youthful sense of inquiry. In that practice we may not open the doors to everlasting science, but we may close the doors to everlasting ignorance.

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